Tomoko Shimakawa, Sc.D. Division of Nutrition Programs and Labeling Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway, HFS-830 College Park, MD 20740-3835

Re: Docket: 2004Q-0151 - Qualified Health Claim: Soy Protein and Cancer

Dear Dr. Shimakawa:

Without a doubt I have a multi-nodular goiter as a result of high soy protein consumption in January of 2004. I had begun consuming a high protein diet supplemented with Soy Protein Product including Soy Protein Powder for baking and Soy milk for drinking.

Never had I consumed soy protein previous to this. Within three weeks I was beginning to feel and see the side effects such as hair loss, brittle nails, hot flashes, chills, noxiousness, fatigue, insomnia, weight gain, and general ill feeling, not to mention depression.

Even though my blood test came back within the healthy range, my doctor found my thyroid to be slightly enlarged upon physical exam and brilliantly requested an <u>Ultrasound which documented my Multi-Nodular Goiter in March of 2004.</u>

I am writing to protest the proposed soy-protein-prevents-cancer health claim and to request that the FDA hold a public hearing on this matter.

The FDA needs to have conclusive significant testing of Soy Product Consumption effects on the Thyroid health of people including ultra sounds for multi-nodular goiters.

I am deeply troubled by the prospect of a soy protein/cancer health claim for the following reasons:

- . The plant estrogens (isoflavones) contained in soy protein products can cause thyroid damage, reproductive disorders and other endocrine disruption.
- . Soy is one of the top eight allergens, and its increased presence in the food supply would jeopardize the health and lives of many Americans.
- . Several subsets of the population are at special risk, including people suffering from hypothyroidism and cancer. There is no consensus among experts that soy prevents cancer.
- . Substantial evidence exists showing that soy can contribute to or even cause cancer, including breast cancer.
- . Cancer statistics and epidemiological studies suggest that soy protein consumption might contribute to lower rates of some types of cancer but to higher rates of other types of cancer.

For the above reasons, I urge the FDA to hold a public hearing on soy protein and to reject the proposed qualified soy-prevents-cancer health claim. And I further request that the FDA perform substantial testing on the effects of Soy Protein Consumption on the health of the human Thyroid and make the conclusive results public.

Thank you,

Mrs. Melissa C. DeVol 11209 Watson Drive Moorpark, CA 93021 805-529-9579